GENTEAL TEARS MODERATE PRESERVATIVE FREE- dextran 70, hypromellose 2910 solution/drops

Alcon Laboratories, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active Ingredients	Purpose
Dextran 70 0.1%	Lubricant
Hypromellose 2910 0.3%	Lubricant

Uses

• temporary relief of discomfort due to minor irritations of the eye, or to exposure to wind or sun

Warnings

For external use only

Do not use

- if this solution changes color or becomes cloudy
- if you are sensitive to any ingredient in this product

When using this product

- to avoid contamination, do not touch tip of container to any surface
- do not reuse
- once opened, discard

Stop use and ask a doctor if

you experience any of the following:

- eye pain
- changes in vision
- continued redness or irritation of the eye
- condition worsens or persists for more than 72 hours

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

• put 1 or 2 drops in the affected eye(s) as needed.

Other information

• store are room temperature $15^{\circ} - 25^{\circ} \text{ C } (59^{\circ} - 77^{\circ} \text{ F})$

Inactive ingredients

potassium chloride, purified water, sodium borate, sodium chloride. May contain hydrochloric acid and/or sodium hydroxide to adjust pH.

Questions?

In the U.S. call 1 (800) 757-9195 (Mon-Fri 9AM-5PM CST) alcon.medinfo@alcon.com

PRINCIPAL DISPLAY PANEL PRESERVATIVE FREE

Moderate DRY EYE SYMPTOM RELIEF

GenTeal* TearsLUBRICANT EYE DROPS

LIQUID DROPS

Fast, Soothing Relief Preservative Free Formula

Previously TEARS NATURALE* FREE LUBRICANT EYE DROPS

STERILE 36 Single-Use Vials 0.9 mL (0.03 FL OZ) Each

Alcon®

GenTeal* Tears Lubricant Eye Drops Preservative Free provide lasting relief for moderate dry eye with the convenience of a vial.

TAMPER EVIDENTY:

Do not use if vial is damaged or opened.

Distributed by: Alcon Laboratories, Inc., 6201 South Freeway Fort Worth, Texas 76134 a Novartis company

Country of Origin: France

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W9012667-1115



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PRESERVATIVE FREE

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GENTEAL TEARS MODERATE PRESERVATIVE FREE

dextran 70, hypromellose 2910 solution/ drops

Product Informa	tion
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Product Type HUMAN OTC DRUG Item Code (Source) NDC:0065-8063

Route of Administration OPHTHALMIC

Active Ingredient/Active Moiety Ingredient Name Basis of Strength Strength Hypromellose 2910 (4000 Mpa.s) (UNII: RN3152OP35) (Hypromellose 2910 (4000 Mpa.s) - UNII:RN3152OP35) Hypromellose 2910 (4000 Mpa.s) and Mpa.s) 3 mg in 1 mL Dextran 70 (UNII: 7SA290YK68) (Dextran 70 - UNII:7SA290YK68) Dextran 70 1 mg in 1 mL

Inactive Ingredients				
Ingredient Name	Strength			
Potassium Chloride (UNII: 660 YQ98 I10)				
Water (UNII: 059QF0KO0R)				
Sodium Borate (UNII: 91MBZ8H3QO)				
Hydrochloric Acid (UNII: QTT17582CB)				
Sodium Hydroxide (UNII: 55X04QC32I)				
Sodium Chloride (UNII: 451W47IQ8X)				

]	Packaging				
7	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
	NDC:0065-8063- 01	36 in 1 CARTON	12/22/2017		
	L	.9 mL in 1 VIAL, SINGLE-DOSE; Type 0: Not a Combination Product			

	Marketing Infor	mation		
ı	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

OTC monograph final	part349	12/22/2017	

Labeler - Alcon Laboratories, Inc. (008018525)

Establishment			
Name	Address	ID/FEI	Business Operations
Kaysersberg Pharmaceuticals		267486052	manufacture(0065-8063)

Revised: 11/2020 Alcon Laboratories, Inc.